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09/624,670	07/24/2000	Pradip Mukerji	6407.US.p2	7619

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/624,670

Applicant(s)

MUKERJI ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-47 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,25-46 and 49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-15, 17-22, 24 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,47 and 50-53 is/are rejected.
- 7) ☒ Claim(s) 16 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: _____

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DETAILED ACTION

Status of the Application

Claims 1, 2-47, 49-53 are pending.

Applicant's amendment of claims 1, 3-5, 8, 15, 23-24, 47, 49, cancellation of claims 2, 48, and addition of claims 50-53 in Paper No. 18, filed on 5/6/2003 is acknowledged.

Applicant's submission of a declaration under 37 CFR 1.131 by Amanda Leonard on 5/6/2003 is acknowledged.

Applicants assert in the specification that SEQ ID NO: 63 and SEQ ID NO: 64 correspond to polypeptides encoded by the polynucleotides of SEQ ID NO: 5 and SEQ ID NO: 6, respectively. As such, claims 50-53 are drawn to the elected invention and will be examined in the instant application. As indicated in previous Office Action Paper No. 14, mailed on 12/17/2002, claims 6-7, 25-46 and 49 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected without traverse in Paper No.12, filed on 10/22/2002. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 3/21/2003 was filed after the mailing date of the first Office Action on the merits, forwarded to Applicants on 12/17/2002.

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The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

2. Claim 16 is objected to because of the following informalities: for clarity, it is suggested that the term "said vector of claim 15" be replaced with "the vector of claim 15". Appropriate correction is required.

3. Claim 23 is objected to because of the following informalities: for clarity, it is suggested that the term "expression of said polynucleotide of said vector" be replaced with "expression of the polynucleotide of said vector" or "expression of the polynucleotide in said vector".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3-5, 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 47 (claims 3-5 dependent thereon) are indefinite in the recitation of "an isolated polynucleotide comprising or completely complementary to the nucleotide sequence of SEQ ID NO" as it is unclear and confusing. While a polynucleotide can comprise a nucleotide sequence, it is unclear as to how a polynucleotide can be completely complementary to a

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sequence. As indicated in previous Office Action Paper No. 14, mailed on 12/17/2002, a sequence is a graphical representation of the order in which nucleotides/amino acids are arranged in a molecule. Therefore, it is unclear as to how a polynucleotide, which is a molecule, can be complementary to a sequence, which is a graphical representation of a molecule. It is suggested that the term be amended to recite "an isolated nucleic acid selected from the group consisting of: (a) a nucleic acid comprising the polynucleotide of SEQ ID NO: #, and (b) a nucleic acid completely complementary to the polynucleotide of (a)", or similar. For examination purposes, the suggested language will be used. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 50-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the polypeptides of SEQ ID NO: 63 or SEQ ID NO: 64, does not reasonably provide enablement for (1) polynucleotides encoding polypeptides having elongase activity wherein said polypeptides are at least 70% sequence similar to the polypeptides of SEQ ID NO: 63 or 64, or (2) polynucleotides encoding polypeptides having elongase activity wherein said polypeptides are at least 60% sequence identical to the polypeptides of SEQ ID NO: 63 or 64. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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9. This rejection, which has been discussed at length in Paper No. 14, was applied to claims 1, 4-5 and 47 and is now applied to claims 50-53 for the reasons of record.

10. Applicants argue that amendments to the claims have been made which address the instant rejection. As such, applicants request the rejection be withdrawn.

Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection in regard to newly added claims 50-53. Claims 50-53 are directed to polynucleotides which encode elongases wherein said elongases have (1) at least 70% sequence similarity to the polypeptides of SEQ ID NO: 63 or 64, or (2) at least 60% sequence identity to the polypeptides of SEQ ID NO: 63 or 64. While the specification discloses the structure and function of the polypeptides of SEQ ID NO: 63 and 64, there is no disclosure of the critical structural elements required in a polypeptide to have elongase activity, nor there is disclosure of which are the amino acids which can be substituted, deleted or inserted in the polypeptides of SEQ ID NO: 63 or 64 to create 60% or 70% structural homologs which retain elongase activity.

In addition, while the specification discloses other polypeptides having elongase activity from other organisms and Applicants assert in the response, page 6, last paragraph, that MELO4 (SEQ ID NO: 63) and MELO7 (SEQ ID NO: 64) share 58.9% sequence identity and 67.7% sequence similarity, it is noted that there is no information as to whether the conserved amino acids among these elongases correlate with function, nor there is information as to whether the non-identical/non-conserved residues can be deleted or substituted with any amino acid and still retain function. As indicated in previous Office Action Paper No. 14, the state of the art teaches the unpredictability of assigning function based on structural homology and how small structural changes can lead to major changes in function. See particularly the teachings of Broun et al.,

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Van de Loo et al. and Seffernick et al. already discussed. Moreover, Witkowski et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β -ketoacyl synthase into a malonyl decarboxylase and completely eliminates β -ketoacyl synthase activity. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to display elongase activity, and the unpredictability of the prior art in regard to assigning function based on structural homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate polynucleotides which encode structural homologs of the polypeptides of SEQ ID NO: 63 or SEQ ID NO: 64, as encompassed by the claims, wherein said homologs display elongase activity. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1, 3-5, 8-9, 11-17, 19-22 and 47 were rejected under 35 U.S.C. 102(a) as being anticipated by Tvrdik et al. (J. Cell Biol. 149(3):707-717, May 2000; GenBank accession number AF170908).

13. This rejection has been discussed at length in Paper No. 14, mailed on 12/17/2002.

14. Applicants submit that the instant invention was conceived and reduced to practice prior to the publication date of Tvrdik et al. (May 2000) as evidenced by a declaration under 37 CFR 1.131 by Amanda Leonard. As such, Applicants request withdrawal of the instant rejection.

15. It is noted that newly added claims 50-53 would be rejected under 35 USC 102(a) as being anticipated by Tvrdik et al. However in view of Applicant's submission of a declaration stating that the instant invention was conceived and reduced to practice prior to the publication of the cited reference, this rejection is hereby withdrawn.

16. Claims 1, 4-5 and 47 were rejected under 35 U.S.C. 102(b) as being anticipated by Izhizaka et al. (EPO publication number EP 0285405, October 5, 1988; GenEMBL accession number 105465).

17. This rejection has been discussed at length in Paper No. 14, mailed on 12/17/2002.

18. Upon further consideration and in view of the amendments to claims 1, 4-5 and 47, which are now drawn to the polynucleotide of SEQ ID NO: 5 and the complete complement of a nucleic acid comprising SEQ ID NO: 6, this rejection is hereby withdrawn.

Claim Rejections - 35 USC § 103

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20. Claims 10 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tvrdik et al. (J. Cell Biol. 149(3):707-717, May 2000; GenBank accession number AF170908).

21. Claims 23 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tvrdik et al. (J. Cell Biol. 149(3):707-717, May 2000; GenBank accession number AF170908) in view of Lassner et al. (The Plant Cell 8:281-292, 1996; cited in the IDS).

22. These rejections have been discussed at length in Paper No. 14, mailed on 12/17/2002.

23. Applicants submit that the instant rejections have been overcome in view of a declaration under 37 CFR 1.131 by Amanda Leonard, which establishes that the nucleic acids of SEQ ID NO: 5 and 6 encoding the MELO4 and MELO7 enzymes were isolated prior to the publication date of the reference by Tvrdik et al. Furthermore, Applicants submit that the declaration actually evidences the construction of the vector as well as the transformation of a cell with such vector. In addition, the reference by Lassner et al. does not teach the claimed invention unilaterally. As such, Applicants request withdrawal of the instant rejections.

24. In view of Applicant's submission of a declaration stating that the instant invention was conceived and reduced to practice prior to the publication of the cited reference, and further in view of the fact that Lassner et al. does not teach the polynucleotides of the instant invention, these rejections are hereby withdrawn.

Double Patenting

25. It is noted that the application Serial No. 10/120637 discloses a polynucleotide (SEQ ID NO: 22) which is identical to that of SEQ ID NO: 1 of the instant application. Since application Serial No. 10/120637 is not available to the examiner at this time, no determination has been made as to whether or not a double patenting rejection should be applied to the claims of the instant application. If, upon availability of the above application to the examiner, it is

determined that there are conflicting claims between application Serial No. 10/120637 and the instant application, double patenting will not be considered as new ground(s) of rejection.

Allowable Subject Matter

26. Claims 8-15, 17-22, 24 appear to be allowable over the prior art of record.
27. Claims 1, 3-5 and 47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
28. Claims 16 and 23 would be allowable if rewritten to overcome the objections set forth above.

Conclusion

29. Applicant's amendment of claims 1, 3-5, 8, 15, 23-24, 47, 49 and addition of claims 50-53 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

31. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 11, 2003

[Handwritten signature]
/s/